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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,225	01/08/2001	Miri Blank	BLANK 3	7300

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EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/743,225	Blank
Examiner	**Art Unit**
David Lukton	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 4, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-21* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Pursuant to preliminary amendment, claims 16, 18, 19 have been amended to correct claim dependence; claims 2-5, 10, 14, 15 have also been amended.

*

A restriction is imposed, as set forth below. First, however, the following subgenera are defined:

G1: this subgenus is limited to peptides, cyclic derivatives of the peptides, and peptides in which one or more D-isomers is present.

G2: this subgenus is limited to "chemical derivatives" of peptides (as recited in claim 2, part (iv))

G3: this subgenus is limited to a multichain peptide-oligmer /polymer conjugate (as recited in claim 2, part (v))

G4: this subgenus is limited to a multiple antigen peptide (as recited in claim 2, part (vi))

G5: the peptide or "derivative" thereof is, or contains one of the following sequences
T-P-R-V, K-A-T-F, L-R-V-Y

*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1, 16, 17, wherein the peptide or derivative thereof can be whatever the claims permit, as long as G5 is excluded.

¥16-17

2. Claims 1-5, limited to G1 and G5.

3. Claims 1, 2, 6, 16, 17 limited to G2 and G5.

4. Claims 1, 2, 7-12, 16-17 limited to G3 and G5.

5. Claims 1, 2, 13-17, limited to G4 and G5.

6. Claim 18, drawn to a method for treatment of anti-phospholipid syndrome by administering a peptide or derivative according to Group 1.

7. Claim 18, drawn to a method for treatment of anti-phospholipid syndrome by administering a peptide or derivative according to Group 2.

8. Claim 18, drawn to a method for treatment of anti-phospholipid syndrome by administering a peptide or derivative according to Group 3.

9. Claim 18, drawn to a method for treatment of anti-phospholipid syndrome by administering a peptide or derivative according to Group 4.

10. Claim 18, drawn to a method for treatment of anti-phospholipid syndrome by administering a peptide or derivative according to Group 5.

11. Claim 19, drawn to a method for inactivating B cells by administering a peptide or derivative according to Group 1.

12. Claim 19, drawn to a method for inactivating B cells by administering a peptide or derivative according to Group 2.

13. Claim 19, drawn to a method for inactivating B cells by administering a peptide or derivative according to Group 3

14. Claim 19, drawn to a method for inactivating B cells by administering a peptide or derivative according to Group 4.

15. Claim 19, drawn to a method for inactivating B cells by administering a peptide or derivative according to Group 5.

16. Claims 20-21, drawn to a kit which contains a peptide according to Group 1.

17. Claims 20-21, drawn to a kit which contains a peptide according to Group 2.

18. Claims 20-21, drawn to a kit which contains a peptide according to Group 3.

19. Claims 20-21, drawn to a kit which contains a peptide according to Group 4.

20. Claims 20-21, drawn to a kit which contains a peptide according to Group 5.

The claimed inventions are distinct.

Inventions 1-5 and 16-20 differ in part because of the (potential) requirement for an apparatus, such as an ELISA plate. Alternatively, inventions 16-20 and 1-5 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). The kit represents a "combination" since (as explained on page 14, line 6+) the kit could contain two peptides according to claim

2, rather than just one, or the kit could contain other anti *beta-* 2-GPI mAb inhibitory peptides. However, in the event that one of Groups 1-5 were elected, and claims therein found allowable, novelty would likely accrue to claims that are drawn to a kit.

Inventions 1-5 and 6-15 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). Nevertheless, in the event that any of Groups 1-5 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination [*In re Ochiai* (**37** USPQ2d 1127)].

Apart from the matter of "peptides" *verus* "kits" and peptides *versus* methods of using them, further rejoining of non-elected embodiments would be likely in the event that Group 2 were elected, and claims therein found allowable. However, there are some embodiments within Groups 4 and 5 which might <u>not</u> be novel. By way of hypothetical example, sppose that the following two tetrapeptides are novel:

T-P-R-V and K-A-T-F

Suppose further that a given protein is known in the prior art which contains both of the sequences TPRV and KATF. Such a reference, if it existed, would anticipate claim 2, part (v). To take another example, suppose that the tetrapeptides TPRV and

KATF are novel, but that the following two peptides (14-mers) are known in the prior art (X1 - X10 represent amino acids):

X1-X2-X3-X4-X5-**T-P-R-V**-X6-X7-X8-X9-X10

X1-X2-X3-X4-X5-**K-A-T-F**-X6-X7-X8-X9-X10

Suppose further that a reference provided motivation to link these two peptides (the 14-mers) to a single carrier. The two references combined might render claim 2 obvious, at least with respect to claim 2 part (v) or (vi). This is because the additional amino acids (X1 - X10) could perhaps be viewed as part of the carrier, or the "core" or a "linker". Whether or not novelty would accrue would depend on how the various terms were defined. Accordingly, in the event that Group 2 is elected, and claims found allowable, it is not necessarily the case that 100% of all embodiments within the scope of Groups 4 and 5 would be rejoined; the matter would have to be revisited at a later time.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific peptide or peptide

derivative which is defined as fully as possible. Note that a "specie" does not "comprise" anything, and a "specie" is not bonded to an unidentifed physical entity.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

The "371" status of the application is acknowledged. However, an applicant filing a national stage application does not enjoy "immunity" from restriction. If the claimed invention does not "define a contribution" over the prior art, then a restriction may be justified. While it may be true that the specific tetrapeptides recited in claim 2 are novel, it is unclear as to the upper limit on the total number of amino acids which may be present in the sequence. The assertion is that peptides and proteins which contain the tetrapeptides are known in the prior art. Accordingly, the claims in their present form do not "define a contribution" over the prior art. Following is the relevant section of the MPEP:

MPEP 1850

PCT Rule 13.2, as it was modified effective 01 July 1992, no longer specifies the combinations of categories of invention which are considered to have unity of invention. Those categories, which now appear as a part of Annex B to the Administrative Instructions, has been substituted with a statement describing the method for determining whether the requirement of unity of invention is satisfied.

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Independent and Dependent Claims.
Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

✺

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.